REMARKS

Claims 1-36 remain in the application.

Invention Synopsis

The present invention is directed to a nutritional formula comprising carbohydrate, protein, and lipid, wherein the lipid contains polyunsaturated fatty acids and from about 0.25 to about 11 ppm, by weight of the total oil content of the formula, of a combination of lutein, lycopene, and beta-carotene, with preferred weight ratios of the lutein to beta-carotene of from about 0.0196:1 to about 59:1, the lycopene to beta-carotene of from about 0.00805:1 to about 114:1, and the lutein to lycopene of from about 0.0117:1 to about 108:1.

This invention is directed to the reduction of carotenoid hues in infant formulas and other nutritional compositions. This is accomplished by using select combinations of lutein, lycopene, and beta carotene, which it has been discovered can be used at low concentrations for carotenoid color reduction without a corresponding reduction in antioxidant efficacy as described herein.

Art Rejection

Bodor et al. in view of Zimmer

Claims 1-7, 12-17, 25-36 have been rejected under 35 USC 103 as unpatentable over Bodor et al. (WO 02/41711) in view of Zimmer (US 2003/0228392). The Examiner contends that it would have been obvious to modify the ratio and concentration of carotenoids (lutein, lycopene, beta carotene) in the Bodor et al. formulations, including the infant formulas disclosed by Zimmer, to thereby realize the claimed invention. Applicants respectfully traverse this rejection.

Bodor et al. disclose edible compositions comprising at least 15 mg/kg of colored carotenoids (p 3, lines 26-27), including beta-carotene, alpha-carotene, lutein, and lycopene (p. 7, lines 7-8). To minimize carotenoid discoloration, the compositions further comprise large particulates (p. 8, lines 26-27). These particulates may

include encapsulated carotenoids (p. 9, lines 10-11) or free carotenoids with either aerated particulates (p. 11, lines 21-23) or water particulates in a water-in-oil emulsion (p. 12, lines 12-15). The Bodor et al. reference does not disclose carotenoid concentrations less than 15mg/kg (15 ppm).

Bodor et al. teach the use of encapsulated carotenoids, or other large particulates, to minimize carotenoid hues. Although the present invention is likewise directed to the reduction of carotenoid hues, this is accomplished in the present case by using lutein, lycopene, and beta-carotene combinations, which it has been discovered can be used at low concentrations for color reduction without a corresponding reduction in antioxidant efficacy.

As to the secondary reference, Zimmer discloses infant formulas comprising 6-230 mcg/Liter of lutein and zeaxanthin (p. 2, para. 0015). Zimmer exemplifies an infant formula with 25 mcg/Liter of lutein and zeaxanthin and 400 IU/Liter of beta-carotene (p. 2, para. 22). The Zimmer reference does not disclose lycopene.

Neither reference teaches a combination of lutein, lycopene, and beta-carotene at concentrations less than about 11 ppm by weight of the total oil component in a composition. Although Bodor et al. teach the combination, they only do so at higher concentrations of at least 15mg/kg (approximately 15 ppm) by weight of the total composition. And when calculated by weight of the oil component in the composition, the minimum carotenoid concentration as taught by Bodor et al. is even higher than 15 ppm. By contrast, the present invention is limited in its broadest aspect to a total carotenoid concentration of from about 0.25 to about 11 ppm by weight of the oil component.

As to the Zimmer reference, it teaches combinations of lutein, zeaxanthin, and beta-carotene (see Zimmer, para 0022, Example 1), but fails to suggest a combination with lutein, beta-carotene, *and lycopene*, the combination to which all claims in the present invention are limited.

The Examiner points out, however, that it would have been obvious to vary the

concentration and ratios of the different carotenoids to achieve the desired fortification. The Examiner further suggests that it would also have been obvious to modify these concentrations and ratios with the intention of achieving the desired carotenoid hue, i.e., lower carotenoid concentrations should produce lighter colors.

The Examiner makes a good point. However, what was surprising about the present invention was the oxidative stability provided by the carotenoid blend even at lower concentrations. As blend concentrations dropped and carotenoid hues lightened, the oxidative stability provided by the low concentration blends was maintained.

To that point, Applicants have shown that oil systems containing 2.11 ppm of a carotenoid blend (lutein + lycopene + beta carotene) are more effective than just 2.11 ppm of beta-carotene, and as effective as 12 ppm of beta-carotene, in resisting peroxide formation and oxidation (see Applicants' Specification at page 21, para 6, and Figures 1 and 2).

Applicants also showed, in a similar study, that an oil system containing 2.5 ppm of the carotenoid blend was as effective as an oil system containing 12 ppm of beta-carotene in protecting against oxidation under the study conditions. The sample containing 12 ppm beta-carotene had an average OSI value of 11.13 (RSD = 2.3%) while the sample containing 2.5 ppm of the carotenoid blend had an average OSI value of 11.07 (RSD = 1.9%) (see Applicants Specification at p. 22, para 3, and Figure 3)

Applicants also showed similar results when the different carotenoid compositions were subjected to sensory evaluations (see Applicants' Specification, p. 22, Sensory Evaluation Table).

Applicants submit that the above data demonstrate unexpected results for carotenoid blends comprising lutein, lycopene, and beta-carotene at concentrations ranging from about 0.25 to about 11 ppm by weight of the oil component of the composition. In other words, neither reference suggests that a carotenoid blend

can be reduced to less than about 11 ppm by weight of the oil component, with a corresponding reduction in carotenoid hues but without a reduction in anti-oxidant properties.

Applicants respectfully request withdrawal of this rejection in view of the foregoing remarks.

Bodor et al. in view of Zimmer and Biji et al.

Claims 8-11 and 18-24 have been rejected under 35 USC 103 as unpatentable over Bodor et al. (WO 02/41711) in view of Zimmer (US 2003/0228392) and Biji et al. (US 6,727,373). The Examiner contends that it would have been obvious to modify the carotenoid formulations of Bodor et al. with the addition of the polyunsaturated fatty acids of Zimmer and Biji et al., to thereby realize the claimed invention. Applicants respectfully traverse this rejection.

Biji et al. disclose microbial oils and methods for obtaining them. The oils contain polyunsaturated fatty acids and are suitable for use in various nutritional products e.g., milk, health drinks, break, infant formulas (see Biji et al. at col. 6, lines 12-16). Some of the Biji et al. oils further comprise 0.15 mg/ml of beta-carotene and 5 mg/ml of gamma-carotene as a by-product of the extraction process (see Biji et al. at col. 23, lines 64-67 and col. 24, lines 1 and 2).

The Biji et al. reference was cited in the Office Action for its teaching of infant formulas with polyunsaturated fatty acids.

Applicants submit that the claimed invention is patentably unobvious in view of Bodor et al., Zimmer, and Biji et al., for the same reasons set forth herein to distinguish over just Bodor et al. and Zimmer.

Although Biji et al. disclose beta and gamma carotene in some of its polyunsaturated fatty acid oils, it fails to suggest the carotenoid blend (lutein, lycopene, and beta-carotene) to which all claims in the present application are

limited. And when carotenoids are disclosed (see Biji et al. at col. 23, lines 64-67 and col. 24, lines 1 and 2) in the oils, the total carotenoid concentration is 5.15 mg/ml, or 5150 ppm by weight of the oil, which is much higher than even the broadest range recited in the present claims (from about 0.25 to about 11 ppm by weight of the oil).

Although it is known that polyunsaturated fatty acids such as those disclosed by Biji et al. are oxidatively unstable, even when formulated into an infant formula, it was not previously known that low concentrations of lutein, lycopene, and beta-carotene could be used to provide oxidative stability to these formulas, which concentrations are even more effective than higher concentrations of beta-carotene when used alone (see earlier discussion of oxidative stability data).

Applicants respectfully request withdrawal of this rejection in view of the foregoing remarks.

Conclusion

Applicants respectfully request reconsideration of this application, withdrawal of all pending rejections, and allowance of claims 1-36.

Respectfully submitted,

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